Written Statement for the Record
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On the
Practicality and Affordability of Aggregating Pharmaceutical Products at the Unit Level on Packaging Lines

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Walter Berghahn is President of SmartRMeds For Life and Executive Director of The Healthcare Compliance Packaging Council, a trade association dedicated to improving medication adherence and patient safety in the U.S. pharmaceutical supply chain through broad adoption of innovative packaging and technology. Walter is grateful to the Committee for considering his comments as it examines measures to secure the drug distribution system.

Walter has worked for over 25 years in the Packaging and Pharmaceutical industries. He offers a unique perspective on the needs of drug manufacturers and patients due to his intimate knowledge of drug packaging and his broad range of experiences throughout the supply chain. Walter's previous projects have focused on: Track and Trace, pedigree, serialization, institutional use of packaging (from hospitals to long-term care), automation integration, electronics integration in packaging, and patient adherence monitoring.

Executive Summary

This statement is an elaboration on data provided in March 2012. The content has been updated to reflect current state of industry readiness.

This written statement is intended to explain that serialization and tracking at the unit level is practical and affordable for the pharmaceutical industry, as demonstrated by millions of transactions taking place on a daily basis in other industries.

Unit level tracking is the only practical way to improve supply chain visibility of individual units which can reduce instances of counterfeiting, diversion and unsafe prescription drug activities. Unit level tracking with bar code serialization is best accomplished through the process of aggregation, whereby multiple containers of like drugs are grouped into larger cases for distribution in the supply chain. The serialized case ID's relate to the serialized unit ID's (parent / child relationship) in data which is only visible to targeted supply chain partners through secure business transactions. Diverted product will show up "out of position" in the supply chain and counterfeiters will not know the numbering scheme nor where the serialized containers were sold making it virtually impossible to introduce product in the legitimate supply chain.

Pharmaceutical manufacturers regularly use bar coding in current process. Each unit of saleable product must have the NDC (National Drug Code) present on the container in Code 128 format. What the California law (SB 1307) is doing is simply requesting to modify that form to a 2D data matrix code which can handle more data and hold a serial number for each unit in the market making them truly unique and therefore traceable in the supply chain. Many manufacturers can repurpose existing equipment on their packaging lines to upgrade for unit level serialization. Cost estimates will vary depending on the company's serialization solution. **Manufacturers can expect to pay from $364,000-$640,000 for the necessary line equipment, software & data configuration, and implementation costs.**

These cost estimates are for a manufacturer to retrofit its first packaging line for serialization with aggregation capability. Subsequent lines would be less expensive. It is important to note that an upgrade for unit-level serialization without aggregation would be 56%–77% of these estimates. Therefore companies serializing product will already cover the majority of costs. The smaller additional investment to achieve aggregation not only will provide financial benefits to the company but will reduce risks to patient safety.

Overview and Existing Technology

Industry and regulatory organizations have been considering a serialization and traceability system for years. Most proposals involve serializing drug products at the smallest saleable unit. Among these, there are two opposing approaches regarding how drugs should be tracked:

- **Unit serialization with required tracking at the *unit* level.** This approach would enable supply chain visibility from the pharmacist back to the manufacturer for every discrete saleable drug product. The California e-Pedigree law, as well as other proposals federally advanced, would require this approach.
- **Unit serialization with required tracking at the *lot* level.** This approach would provide supply chain visibility between the manufacturers and distributors for every pharmaceutical product lot. These lots can vary in size and represent hundreds of thousands of different drug products created over long stretches of time. Pharmacists, however, would not be required, and in most cases would not be able to, authenticate an individual drug product.

Unit level serialization and tracking would not require the pharmaceutical industry to develop new or complex technologies. Rather, it would involve the adoption and repurposing of existing technologies to protect consumers of drug products.

Further, several industries already depend on the ability to track and authenticate millions of unique IDs daily. Retail stores and warehouses across America have been using a parallel technology, barcode scanning, for decades to manage their inventories. Even hospitals, including the VA, rely on barcodes to properly administer medications.

Express delivery industry tracks over 23 million serialized units per day

In 2011, the two biggest express delivery companies in the U.S. (Fed Ex, UPS) shipped, on average, a combined daily total of 23 million units, all of which relied on serialization and tracking technologies.

Credit card industry authenticates over 64 million transactions per day

Estimates show that credit card companies authenticate approximately 64 million credit card transactions daily. This estimate excludes account transactions for debit and ATM cards. Each card swipe is authenticated in real time via secure databases.

Airline industry authenticates over 1.5 million passengers per day

Approximately 1.5 million passengers board a plane in the U.S. daily. These passengers carry a boarding pass with a bar code, which verifies who they are and confirms that they belong on the flight.

The California law, if applied federally, would require pharmacies to track and authenticate 11 million prescriptions per day

Pharmacists scan drugs at the unit level every day. The vast majority of U.S. pharmacies use a bar code scanner to read the National Drug Code (NDC) number, which is on every saleable unit**.** Also, pharmacies use bar codes on prescriptions to identify patients in their databases and to link prescribed products to the actual prescriptions.

Further, national figures, on average, show that independent pharmaceutical stores fill 200 prescriptions per day, while large retail chains fill about 300 per day. Adding serialized containers to this process would not involve additional scans. Rather pharmacists would substitute one type of scan (NDC) for another (SGTIN), which may require upgrading or modifying scanning equipment.

Supply Chain Visibility With Unit Level Tracking

Supply chain visibility with unit level tracking would reduce the likelihood of counterfeits, product diversion, and gray market activity, and would allow for targeted recalls and returns reconciliation. Similar reductions cannot be achieved using the lot level approach.

Aggregation – the process of grouping similar units into larger packages – is the most efficient and cost effective means of providing unit level visibility to products as they move through the supply chain. Aggregation involves creating a unique serial number at each level of packaging to establish parent-child relationships. This way, individual drug units can be identified regardless of how many layers of packaging the unit is encased in.

Most of the arguments for and against unit level tracking are centered on cost. However, lost in this discussion are some of the opportunities that would improve patient safety:

Optional Home Authentication

Unit level tracking opens the door to home based drug authentication. In the future, patients or caregivers could gain peace of mind by scanning a serialized drug unit (with their phone or other scanning device). In theory, an individual could verify that his or her drug indeed came from the pharmacy from which it was purchased and that the drug has a complete and valid chain-of-custody record going all the way back to the manufacturer.

Better Supply Chain Management

Unit level serialization and tracking are the first steps to a safer drug supply chain. Only when stakeholders better understand where and how drugs travel through the supply chain, can they begin monitoring what happened to the drugs during transit. For example, supply chain managers could monitor storage history and transit conditions relative to changes in temperature, which can directly affect drugs' efficacy.

Affordable aggregation solutions for unit level tracking, using proven technologies, exist and can contribute significantly to the safety of consumers and the security of the U.S. pharmaceutical drug supply chain.

Coding Technology and Aggregation In Use Today

There is broad consensus across the pharmaceutical industry that the preferred and most cost-effective means of unit level tracking involves printed 2D data matrix codes. A common argument against unit level tracking is that companies would need to introduce new equipment, which would be too expensive to implement. Most packaging lines, however, are using, and have been using for decades, similar equipment and technology, which includes:

- Printers and coding equipment
- Cameras and inspection equipment

- Reject systems
- Labeling equipment
- Sensors and automation controls

Repurposing existing equipment, when possible, to print and inspect unique codes would allow pharmaceutical companies to serialize at the unit level and comply with the California law. Also, unit level serialization would enable companies to pursue, at their own discretion, additional equipment to monitor drug units as they get aggregated (into a bundle, case, pallet, etc).

Machinery manufacturers are already providing pharmaceutical companies with unit level tracking and aggregation solutions. For example, in 2009, a mid-Atlantic pharmaceutical company sought to manage risks to its internal supply chain. The client worked with a machinery manufacturer to print unique, human-readable codes on the bottom of every bottle. With these codes, the client was able to establish high integrity, parent-child relationships between the case and bundle labels, and the individual bottles.

Currently, the same machinery manufacturer is delivering a custom, end-of-line solution for three carton lines to one of its major pharmaceutical clients with operations in China. The operation involves a unique code being applied to the sides of every carton. The cartons are aggregated, first into a bundle and then into a case. At each level of aggregation, a package receives a unique serialized label that identifies all its constituent cartons.

There are numerous examples of aggregation solutions being deployed across the Pharmaceutical industry, as well as aggregation solutions currently operating in the Automotive, Computer, and Personal Care industries.

Estimated Costs to Upgrade Existing Packaging Lines for Serialization

Unit Level Serialization with Aggregation

Current estimates, from several notable manufacturers and suppliers, indicate that a company will pay from $364,000-$640,000 to retrofit its first packaging line with unit level serialization and aggregation. These figures include one-time expenses, general infrastructure costs, and software licensing fees, all of which a company can leverage to substantially reduce the cost of adding subsequent lines within the same facility.

The vast majority of pharmaceutical products fall into two primary categories: round bottles (solid oral dose and liquids) and cartons (blister packs, vials, syringes, etc). The following cost estimates consider both of these packaging formats under two different upgrade scenarios.

	Low-Complexity Packaging Line Serialization Upgrade	**High-Complexity Packaging Line** Serialization Upgrade
Line Equipment	$70,000	$212,000
Data Servers & Software Configuration	$190,000	$245,000
Implementation	$104,000	$183,000
Unit Level Serialization Upgrade	$364,000	$640,000

* Costs shown are for the initial packaging line

These figures factor in validation, project management, and contingency factors (at 40% of the supplier costs). These costs do not factor in additional serialization expenses at the enterprise level.

The wide cost range reflects two extreme scenarios and should not be interpreted as either-or. Most manufacturers will incorporate aspects from each scenario, depending on the complexity level of their serialization solutions and the availability of existing equipment.

This table is further supported by a recent serialization quote provided to a leading generic pharmaceutical company. The quote, for $512,000, detailed a medium-speed, medium complexity serialization solution for one packaging line including site-level servers.

Unit Level Serialization without Aggregation

Companies can forego the inclusion of aggregation in their unit level serialization solution, but an upgrade to serialization alone would already represent the majority of costs estimated here: 56%–77%. (The additional amount to aggregate is due to some Line Equipment and Implementation costs that are associated with aggregation. The Data Servers & Software Configuration costs would remain the same.) Because there is broad agreement that unit level serialization will become an expectation of our distribution system, I strongly advise that the smaller additional investment to achieve aggregation is well justified. Companies will see financial benefits, and risks to patient safety will be reduced.

Serialization Upgrade Scenarios

Low-Complexity Packaging Lines

This scenario considers companies with lines that are running at low-speed, low-volume. This scenario assumes a company is serializing a simple product (rectangular carton) with manual packing with two levels of aggregation (cartons into cases; cases onto pallets). Here, the serialization upgrade would consist mostly of software modifications to existing labeling equipment. The company would need to purchase some additional cameras and inspection stations and obtain software licenses.

Each unit (carton) would receive a serialized code at the labeling station. The units would travel downstream, ultimately reaching the case packing station. Inspection equipment would scan the serialized unit codes, layer by layer, as the units get loaded into a case having its own serialized label. Once the final layer is loaded and scanned, the case gets sealed, which establishes the parent-child relationship between the case and its constituents. The case would then be scanned and manually placed on a pallet having its own serialized label establishing that next level of aggregation. Each step in this scenario takes advantage of existing packaging operations and label stock requirements with slight modifications.

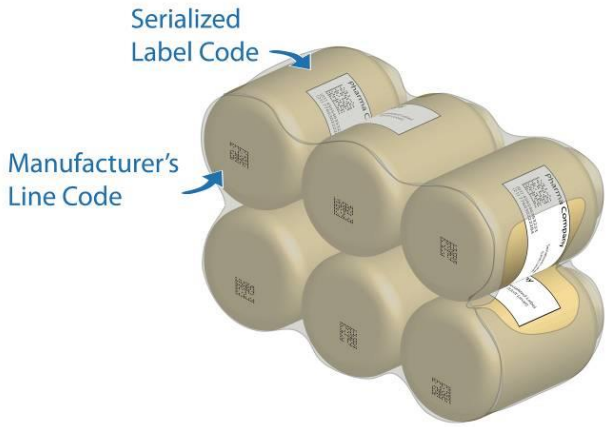
Necessary purchases and upgrades:

- Modify existing labeling equipment for serialization
- Install additional inspection equipment to read serialized codes
- License, implement, and maintain a data management system

High-Complexity Packaging Lines

This scenario considers companies with high-speed, high-volume operations that seek robust tracking of their products throughout a packaging line. This scenario assumes a company is serializing a challenging product (round bottles) with several levels of aggregation (bottles into bundles; bundles into cases; cases onto pallets).

Each unit (round bottle) would get a unique manufacturer's line code printed either on its cap or its bottom. The line code is relevant only to the packaging line and for processing and forensic use. The line code is distinct from the serialized label code (sGTIN), which a pharmacist or other supply chain partner could scan, and which would get applied to the unit further down the packaging line.



Immediately after the serialized label is applied to the unit, custom inspection equipment would synchronize the label with the manufacturer's line code. The units would travel down the packaging line with two unique codes towards a bundling station, which would group and shrink wrap several units into small bundles. A labeling station would apply a unique serialized label to the bundle.

It is important to note that the serialized label codes on round bottles may be blocked or hidden from an inspection camera when the bottles are grouped. However, the manufacturer's line codes would still be visible (on the units' caps or bottoms). Inspection equipment would simultaneously scan the bundle's label code and manufacturer's line codes on all the units to establish the parent-child relationship.

Upon reaching the automatic case packer, each layer would be scanned, either looking for bundle labels or the manufacturer's line codes, while the scanner simultaneously reads the serialized case label. In this manner all layers of bundles would be aggregated to the case establishing the second level of parent-child aggregation.

Lastly, after exiting the case packer, cases would be automatically palletized. A scanner would read the case codes while another system (scanner or RFID reader) simultaneously reads the serialized pallet code (either 2D data matrix or RFID tag), establishing the third and final layer of parent-child aggregation.

The equipment described below provides the highest level of integrity since it enables companies to establish the parent-child relationship *after* the serialized aggregation takes place.

Necessary purchases and upgrades:

- Modify existing labeling equipment for serialization
- Install line printing equipment to place manufacturer's line code on bottle and label on bundle
- Install additional inspection equipment to read serialized codes
- Install post-labeler station to sync the manufacturing and serialized code
- Install end-of-line inspection station and modifications to case packer and palletizer
- License, implement, and maintain a data management system

Industry Momentum

Presently, there is an incredible amount of momentum behind the serialization effort and unit level tracking within the U.S. and abroad. This momentum is evident by flipping through any relevant industry magazine or by attending a packaging trade show. Three demands – the demand for increased patient safety, the demand to meet California's ePedigree Law (SB 1307), and the demand for businesses to compete internationally – are largely responsible for propelling serialization to the industry foreground.

The California Board of Pharmacy has demonstrated exceptional willingness to work with the Pharmaceutical Industry with respect to implementing the e-Pedigree Law. The initial targets were set for 2007 and were subsequently delayed to allow industry time to comply. The pharmaceutical manufacturers now have until January 1, 2015 to serialize 50% of their products. The rest of the supply chain sees staggered implementation ending with pharmacy and pharmacy warehouses in July 2017, which is four years from now. The pharmaceutical industry is actively preparing to meet these deadlines. It is hoped that any federal legislation would be supportive of California SB 1307 and build on their progress.

The supporting packaging machinery industry is well prepared. Various levels of systems ranging from manual to fully automated exist, which can apply, verify, and aggregate 2D bar coded containers in the packaging process. Complete cases exit the packaging process in a pharmaceutical manufacturer or contract packaging plant ready for entry into the supply chain. Companies such as Systech, Optel, Seidenader, Omega Design, Antares, Laetus, PCE, Visiotec and numerous others are actively engaged in delivering these systems to both branded and generic pharmaceutical manufacturers.

Completed and Pilot Lines

As of today, there are nearly 100 U.S. based sites that have met or exceeded the California e-Pedigree requirements. More than 600 are being planned, ordered and constructed. A much larger number have already been deployed globally to meet international requirements for serialization in countries like China, Brazil, Turkey, India and large portions of the EU.

Successful pilots have been running throughout the industry beginning in 2006, such as those lines at Pfizer, Abbott Labs, Purdue Pharma, Glaxo Smith Kline, Novartis, AstraZeneca, among others.

In an effort to save lives and trim costs, the Veterans Health Administration and its Consolidated Mail Outpatient Pharmacy successfully conducted a pilot program from January through September in 2012. During this period, they were able to send drugs throughout the supply chain and to stage a drug recall. They are currently pursuing a second pilot program to continue their work.

Standards and Supply Chain Implementation

GS1 is dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply chain. Their Electronic Product Code Information Services (EPCIS) is ready for industry adoption, which many companies, such as Oracle and IBM, have been willing to manage the e-Pedigree data and transactions.

Summary

Unit level serialization and tracking technology, which is needed to satisfy the California e-Pedigree law, is available and is being managed successfully in other industries. The pharmaceutical industry can realize high-integrity serialization solutions by repurposing or upgrading existing equipment.

For pharmaceutical manufacturers, the cost to upgrade a packaging line for serialization varies relative to the complexity of the company's solution. Nevertheless, affordable options exist.

Unit level serialization, aggregation, and tracking provide many financial benefits. However, the pharmaceutical industry as a whole should make unit level tracking an imperative considering the immense benefits it would bring to patient safety.

Resources

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